

REXHUBER

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Sent: Wednesday, August 21, 2013 1:09 PM
To: Cameron, Roger; Tom Cartmell (External); afaes@wcllp.com; Bryan Aylstock; Ben Anderson
Cc: Kline, Thomas R.; Specter, Shanin; Balefsky, Lee
Subject: RE: TVM/TVT MDL Deposition of Gregory Jones

Great work gentlemen! Sounds like an interesting read!

From: Cameron, Roger [mailto:Roger.Cameron@KlineSpecter.com]
Sent: Wednesday, August 21, 2013 12:00 PM
To: Tom Cartmell (External); afaes@wcllp.com; Bryan Aylstock; Renee Baggett; Ben Anderson
Cc: Kline, Thomas R.; Specter, Shanin; Lee Balefsky (External)
Subject: TVM/TVT MDL Deposition of Gregory Jones

Yesterday Lee and I deposed Gregory Jones, formerly the WW Director of Regulatory Affairs and Quality Assurance for Ethicon/ Gynecare . The deposition took place in Utica NY, Jones's current residence.

Overview:

Jones makes a terrible witness for the Defendants. Despite signing the original 510(k) in 1997 for the TTV device and its truth and accuracy certification, he displayed almost no support for his work or the companies' work. He was not animated at all, rarely looking at the camera. He took an extremely long time to respond to almost every question and looked like he was mentally calculated all of the permutations of his possible answers, rather than answering directly. His aspect was more of not caring in the least about his work. He certainly did not make more than the most minimal efforts to advocate for Gynecare. Even Phil Combs, opposing counsel, commented negatively on Jones' appearance after the dep concluded. Jones made at least several significant admissions that were excellent for plaintiffs. There are several very good clips that can serve both substantively and persuasively in the first TTV trial. We believe our regulatory expert, Peggy Pence, will benefit from a review of the transcript, particularly in his testimony concerning the selection of Boston Scientific's ProteGen as a predicate device and his belief that its recall on safety issues, only a few months after clearance of TTV, made no difference in the marketability of TTV.

Substantive Testimony:

As expected, he recalled very, very little of anything. His responded to the "rules of the road" questions, by saying repeatedly that JnJ/Ethicon had no duty to train doctors on the use of the new, TTV device, that he does not believe that patient safety was the first consideration, and that device manufacturers should be responsible only for purposeful, even criminal, conduct.

He waffled a bit on whether Ulmsten used JnJ/Ethicon's Prolene before Medscand licensed and later sold the product to JnJ/Ethicon. However, his initial answer was that Ulmsten did not, and, as we know, given the timing, Ulmsten could not have used it. Later, he claimed that, and then equivocated, on whether Prolene was used in the clinical examinations that were documented in the reports attached to the TTV 510(k).

He put the entire burden on his subordinate, Peter Cecchini, for collecting the supporting information for and the drafting the 510(k) . Despite being Cecchini's supervisor, he did little more than sign the submission that Cecchini prepared. He cannot recall ever questioning Cecchini on the use of ProteGen as a predicate device. He validated the selection of ProteGen as a predicate device, despite the differences between it and TTV. He said he was not aware of

the ProteGen recall but should have been. And, despite the recall, if he had known of it, he testified that still would not have taken action with respect to TVT.

Lee reviewed with Jones the list of potential complications that were excluded from the proposed IFU.

One clip that may bear building on with other witness involved the surgical needles. His testified that his first position with Gynecare was as second shift supervisor for the needle production line. Maybe that keyed his only distinct memory of the TVT device (pre-clearance), because he noted, with perhaps the most emotion he showed during the entire day, that the needles proposed for its use were "really large," larger than he had seen in his four years in that job.

He supported all of the requirements for an adverse inference on the loss of his custodial files. He testified to the physical presence of extensive files of his work in file cabinets and on his computer. He acknowledged that he should have received the 2003 Hold Notice and that, as far as he knew, it was never rescinded. All of his files and his computer remained in JnJ/Ethicon's possession after he left in 2003. However, despite representations from opposing counsel that Jones left in November, 2003, he could not specifically remember in which month he left.

In quite a few ways, his testimony was strained and left a strong sense that he and the RA department was not competent, as when he refused to admit the Ulmsten had a financial interest in both sales of TVT, acceptable study results, and Medscand. Despite saying that such interests were at some point required to be disclosed in the medical literature publication field, he would not say that it was improper not to have disclosed them in the 510(k) while relying on Ulmsten's clinical information to support clearance.

He did admit that Gynecare had no bench testing data for this 510(k) of elasticity, porosity, burst strength or any of the usual material characteristics. Very reluctantly, he agreed that, in the absence of such data, statements regarding bi-directions elasticity and pelvic floor forces were false.

He could not reconcile the strongly cytotoxic biocompatibility ISO test result for ethylene-oxide sterilized mesh against the not cytotoxic biocompatibility ISO test results for unsterilized mesh, both of which were included in the original 510(k) for TVT. He was not aware of any effort at Gynecare to do so.

As to post-marketing surveillance, he said that, other than receiving monthly reports in the form of spreadsheets, he never had responsibility for the handling of product complaints. He put all of that responsibility on Burkely Pollard.

If you have any questions or want any follow up on this deposition, please let us know.

Thanks,

Roger

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